

REMARKS

Status Summary

Claims 1-33 are pending in the present application. In response to a Restriction Requirement issued by the U.S. Patent & Trademark Office (hereinafter the "Patent Office"), applicants elected Claims 1-8, 11-13 and 15-19 for further prosecution at this time. As such, the Patent Office has withdrawn from consideration Claims 9, 10, 14 and 20-33.

With entry of the present amendment, Claims 1, 3, 6, 8, 11-13, and 16-19 have been amended and Claims 9, 10, 14 and 20-33 have been canceled. Claims 1-8, 11-13 and 15-19 presently stand rejected. New claims 34 and 35 are added by the present amendment. No new matter has been added by the amendments to the present claims or the addition of new claims.

Response to Objection to Information Disclosure Statement

The Patent Office asserts the copy of the reference Guttman, *LC/GC Magazine*, 17:1020-1026, 1999 submitted in applicants' IDS filed July 14, 2004 is deficient in that the copy of the reference provided the Patent Office does not include any of the citation data of the reference, including publication date. The Patent Office has therefore objected to the IDS and requires submission of the complete citation data.

In response, applicants file herewith as attached **Exhibit A** the complete citation data, including publication date (Volume 17, Number 11, November 1999) for the Guttman reference. As such, applicants respectfully request withdrawal of the objection to applicants' IDS filed July 14, 2004.

Response to Objection to Specification

The Patent Office has objected to the specification for allegedly improperly citing the priority data of the application. The changes required by the Patent Office have been made to the specification as indicated by the amendment to the

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specification above. Applicants therefore respectfully request withdrawal of the objection to the specification.

*Response to Objection to Claims*

The Patent Office has objected to Claims 3, 6, 8, 11-13, and 16-19, asserting a comma (,) should be inserted before the word "wherein" in each of these claims. Applicants have amended the objected to claims accordingly and therefore respectfully request withdrawal of the objection to Claims 3, 6, 8, 11-13, and 16-19 and allowance of these claims.

*Response to Claim Rejection - 35 U.S.C. § 112*

The Patent Office has rejected Claims 1-8, 11-13, and 15-19 under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention.

Claims 1, 5-6, 11, and 15 have been rejected under 35 U.S.C. § 112, second paragraph upon the contention that the term "nanoporous" renders the rejected claims indefinite because the metes and bounds for the term are allegedly not defined in the claim language. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

With regard to the term "nanoporous", the Patent Office asserts that it is not clear what limitations the term encompasses. As defined in the instant specification, the term "nanoporous" is used to refer to structures having a network of pores therein. In some embodiments, the diameter of the pores ranges from about 1 nm to about 100  $\mu\text{m}$ . See the instant specification at, for example, page 13, line 14 through p. 14, line 29 and Figures 14 and 16. The specification further teaches the particular nanoporous structure and composition chosen is dependent upon the application for which the nanoporous structure is needed, as would be appreciated by one of skill in the art. The physical dimensions and geometric orientations can be formed into, for

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example, strips, combs, sheets, filters, or various other configurations. See specification at page 14, lines 16-29. Further, the specification teaches the nanoporous structure comprises materials compatible with the particular type of reaction to be performed, including treating or modifying the nanoporous structure prior to a particular use. See specification at page 13, line 25 through page 14, line 8 and Examples 5-11, wherein the selection process of several nanoporous structures for particular applications is taught. Accordingly, applicants respectfully submit that the term “nanoporous” is clearly defined in the instant application when viewed in the context of the specification. However, in an effort to expedite prosecution of the pending claims, applicants have amended Claim 1 to recite a method comprising contacting a first component and a second component with one of a nanoporous membrane comprising pores or a nanoporous bead comprising pores.

Accordingly, the rejection of claims 1-8, 11-13, and 15-19 related to the use of the term “nanoporous” is believed to be addressed. Therefore, applicants respectfully request withdrawal of the rejection. Applicants also respectfully request allowance of the claims.

Claims 3, 6, 8, 11-13, and 16-19 have also been rejected under 35 U.S.C. § 112, second paragraph upon the contention that the term “includes” renders the rejected claims indefinite because it is alleged the term is not clear as to whether it is open like “comprising” or closed like “consisting of”. The Patent Office suggests the term should be replaced with “comprises”. After careful consideration of the rejection and the Patent Office’s bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

The terms “includes” and “including” have been interpreted by the Court of Appeals for the Federal Circuit to be inclusive and “open” terms, synonymous with “comprising” and therefore do not exclude additional, unrecited elements or method steps. See MPEP 2111.03 and *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). As such, applicants respectfully submit the term “includes” is not indefinite, as the Federal Circuit has

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determined the term is synonymous with the open term "comprises". Therefore, applicants respectfully request withdrawal of the rejection of Claims 3, 6, 8, 11-13, and 16-19 on the basis of this rejection. Applicants also respectfully request allowance of the claims.

Claim 7 has been rejected under 35 U.S.C. § 112, second paragraph, upon the contention that the term "kinetic characteristic" renders the rejected claim indefinite because the metes and bounds for the term are allegedly not defined in the claim language. After careful consideration of the rejection and the Patent Office's basis therefor, applicants respectfully traverse the rejection and submit the following remarks.

With regard to the term "kinetic characteristic", the Patent Office asserts that it is not clear what limitations the term encompasses. As taught in the instant specification, the term "kinetic characteristic" is used to refer to a characteristic of a reaction which is influenced or determined in part by at least one kinetic factor. See specification at page 5, lines 5-13. Exemplary kinetic factors discussed in the specification include temperature, concentration, time, pH, volume, pressure, diffusion, material characteristics, and the like. See specification at page 6, lines 10-12 and Claim 8. The specification further defines the term "kinetic characteristic" at page 11, lines 15-22 and page 13, lines 3-5. The specification also teaches the benefits provided by the presently disclosed subject matter at page 24, line 21 through page 26, line 13, including reducing the time for a reaction to proceed to product and reducing the volume required for a successful reaction to occur, for example.

In view of the remarks presented hereinabove, applicants respectfully submit that the rejection of Claim 7 related to the use of the term "kinetic characteristic" has been addressed, and therefore applicants respectfully request withdrawal of the rejection. Applicants also respectfully request allowance of Claim 7.

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Response to Claim Rejection - 35 U.S.C. § 102

Mauck

Claims 1-8 and 15 stand rejected by the Patent Office under 35 U.S.C. § 102(b) based on U.S. Patent No. 5,032,504 to Mauck (hereinafter, "Mauck"). The Patent Office asserts Mauck teaches each and every element of independent Claim 1, as well as the rejected claims depending therefrom. In particular, the Patent Office asserts Mauck teaches a method to contact a chlamydial or gonococcal antigen extracted from a sample with a surfactant coated polyamide microporous membrane having an average pore size of 1 $\mu$ m to 10 $\mu$ m. The Patent Office asserts Mauck further teaches the membrane is also contacted with a chlamydial or gonococcal antibody, wherein the mixture results in an immunological complex.

The contentions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

"A claim is anticipated only if each and every element in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 presently recites a method comprising contacting a first component and a second component with one of a nanoporous membrane comprising pores or a nanoporous bead comprising pores, wherein the first and second components are contacted within the pores and producing a product from a reaction of the first component with the second component. Claim 1 has been amended to more particularly recite that the nanoporous membrane or nanoporous bead comprises pores and that the first and second components are contacted within the pores. Support for the amendment can be found throughout the specification and in particular at page 12, lines 14-17, wherein it states that reactions performed within nanoporous membranes provide favorable reaction conditions to improve kinetic characteristics of the reaction over kinetic characteristics of a reaction in the absence of a nanoporous membrane. See also page 11, lines 28-29 of the specification and

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Figures 14 and 16. The specification teaches that the kinetic characteristics are improved by performing the reaction within the pores of a nanoporous membrane due to “molecular crowding” within the reduced confines of the pores, which effectively increases the local concentration of the reactants, thereby inducing enhanced kinetic characteristics, such as for example rate of the reaction. See specification at page 47, lines 7-16.

Figures 14 and 15 illustrate the advantage provided by the presently disclosed subject matter of conducting a reaction within the pores (Figure 14) compared to without a nanoporous structure (Figure 15). Figure 14 illustrates first and second reactants (**420** and **425**) confined within close proximity in the pores, reacting at a higher local concentration and facilitating increased reaction kinetics. In contrast, Figure 15 illustrates the same reaction occurring in the absence of a nanoporous structure. As can be seen from a comparison of the two figures, the reactants in Figure 15 in the absence of a nanoporous structure have a lower effective concentration and therefore less desirable kinetic characteristics. As taught by the specification, “the bonding is accelerated by the increased effective concentration of components within the confines of the nanoporous structure.” Specification at page 48, lines 17-18.

Mauck, in contrast, does not teach or suggest contacting first and second components within the pores of a nanoporous membrane. Mauck instead teaches contacting chlamydial or gonococcal antigen with a microporous membrane so that the antigen is bound on the membrane and then contacting the antigen with a chlamydial or gonococcal antibody “so as to form an immunological complex on the membrane.” Mauck at column 2, lines 45-46 (emphasis added). Mauck further teaches “determining the presence of the complex on the membrane.” Mauck at column 2, lines 47-48 (emphasis added). The complex is “then detected on the membrane using standard radiometric, colorimetric, fluorescent or other detection techniques.” Mauck at column 7, lines 41-43 (emphasis added). Thus, Mauck does not teach contacting the components within the pores of a nanoporous membrane as

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recited in Claim 1, but rather teaches forming a complex and detecting the complex on the surface of the membrane.

Mauck does not appreciate the enhanced kinetic characteristics of a reaction that can result from facilitating occurrence of the reaction within the pores of the nanoporous membrane, but rather sees the pores of the membrane solely as a means of filtering out waste product. Mauck teaches a microporous membrane coated with a surfactant, which Mauck contends provides an advantage over the prior art in that biological specimens containing whole blood, mucous or components thereof tend to clog the prior art microporous membranes, whereas the surfactant-coated membrane taught by Mauck is not clogged by these materials. See Mauck at column 3, lines 1-8. Coating the membrane with a surfactant, Mauck teaches, allows "fluid and unbound materials (such as whole blood and mucus components) in the specimen ... to flow through the membrane and [collect] in a suitable compartment during the time the antigen is bound to the membrane." Mauck at column 5, lines 47-52 (emphasis added).

Thus, Mauck does not teach contacting first and second components within the pores of the membrane, but rather teaches forming and detecting immunological complexes on the surface of a membrane and only using the pores of the membrane for filtering waste. As such, Mauck cannot anticipate Claim 1 as it does not teach each and every element of presently recited Claim 1. Therefore, applicants respectfully request withdrawal of the rejection of Claim 1 under 35 U.S.C. § 102(b), as being anticipated by Mauck. Allowance of Claim 1 is also respectfully requested.

Since Claims 2-8 and 15 depend either directly or indirectly from Claim 1, and Mauck does not teach or suggest all the elements of Claim 1 for the reasons stated above, Mauck does not teach or suggest all the elements of these dependent claims either. Applicants therefore respectfully request withdrawal of the rejection of Claims 2-8 and 15 on the basis of Mauck. Allowance of these claims is also respectfully requested.

Jacobson et al.

Claims 1, 11-13, and 15-18 stand rejected by the Patent Office under 35 U.S.C. § 102(b) as being anticipated by the journal article to Jacobson et al. (*Analytical Chemistry*, 1996, Vol. 68, pp. 720-723; hereinafter, "Jacobson et al."). The Patent Office asserts Jacobson et al. teaches each and every element of independent Claim 1, as well as the rejected claims depending therefrom. In particular, the Patent Office asserts Jacobson et al. teaches a restriction digestion reaction wherein the DNA plasmid pBR322 is digested with a restriction enzyme in a chip reaction chamber comprising polyacrylamide and the products are subsequently separated in a separating column on the chip. The Patent Office argues the polyacrylamide is the equivalent of the nanoporous structure recited in Claim 1 because "[t]he polyacrylamide is immobilized to the chip so it is in form of a membrane". Official Action at page 5. The Patent Office then relies on U.S. Patent No. 5,370,777 to Guttman et al. (hereinafter, "the '777 Patent'") as evidence to support the premise that the polyacrylamide gel has an average porosity of 80 nm.

The contentions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

"A claim is anticipated only if each and every element in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 presently recites a method comprising contacting a first component and a second component with one of a nanoporous membrane comprising pores or a nanoporous bead comprising pores, wherein the first and second components are contacted within the pores and producing a product from a reaction of the first component with the second component. Claim 1 has been amended to more particularly recite that the nanoporous structure is a membrane or bead comprising pores and that the first and second components are contacted within the pores. Support for the amendment can be found throughout the specification and in



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particular at page 13, lines 14-25, page 14, lines 9-29 and Figures 1-4b, which show one embodiment of a nanoporous membrane, as well as Figure 16, which shows one embodiment of a nanoporous bead.

Jacobson et al. appears to teach an integrated microchip apparatus that can be used for performing a restriction digestion and an electrophoretic sizing experiment of the digested nucleic acids within the same apparatus. See Jacobson et al. at page 720, second column. Jacobson et al. also appears to teach the DNA and enzyme are electrophoretically loaded from their respective reservoirs into a reaction chamber where digestion occurs. After digestion, the digested products are then migrated into a separation channel on the same chip for separation and analysis. See Jacobson et al. at page 722, second column. Jacobson et al. teaches that the electroosmotic flow can be minimized by the covalent immobilization of linear polyacrylamide in the microchip channels. See Jacobson et al. at page 722, second column.

The Patent Office argues the polyacrylamide within the microchip of Jacobson et al. is the equivalent of the claimed nanoporous membrane. Applicants respectfully disagree. Jacobson et al. teaches the polyacrylamide gel acts as a "sieving medium" to minimize electroosmotic flow of the DNA and enzyme. See Jacobson et al. at page 722, second column and page 723, first column. Jacobson et al. does not teach the polyacrylamide gel is a membrane. Further, the instant specification distinguishes between nanoporous membranes and gels. For example, at page 14, lines 9-29 of the instant specification it is taught that nanoporous structures provided by the present application include nanoporous membranes and other structures, including gels and thin layer gels. Claim 1 presently recites a method of using a nanoporous membrane or nanoporous bead, both of which are distinct from gels as defined by the specification.

Accordingly, it is respectfully submitted that, Jacobson et al. does not teach each and every element of Claim 1. As such, applicants respectfully request

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withdrawal of the rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Jacobson et al. Allowance of Claim 1 is also respectfully requested.

Since Claims 11-13 and 15-18 depend either directly or indirectly from Claim 1, and Jacobson et al. does not teach or suggest all the elements of Claim 1 for the reasons stated above, Jacobson et al. does not teach or suggest all the elements of these dependent claims either. Applicants therefore respectfully request withdrawal of the rejection of Claims 11-13 and 15-18 on the basis of Jacobson et al. Allowance of these claims is also respectfully requested.

#### Claim Rejection - 35 U.S.C. § 103

##### Mauck in view of Jacobson et al. and Guttman et al.

Claims 1-8, 11-13, and 15-19 stand rejected by the Patent Office under 35 U.S.C. § 103(a) as being obvious over Mauck in view of Jacobson et al. with evidence provided by the '777 Patent and further in view of the journal article to Guttman et al. (*Electrophoresis*, 2000, Volume 21, pp. 3952-3962; hereinafter, "Guttman et al."). The Patent Office asserts the combination of references teach or suggest each and every element of the rejected claims. The Patent Office further asserts one having ordinary skill in the art at the time of the claimed invention would have been motivated to modify and combine the teachings from Mauck according to the teachings of Jacobson et al. with evidence provided by the '777 Patent and further in view of the teachings of Guttman et al. because Jacobson et al. and Guttman et al. "remedy the deficiencies" of Mauck. See Official Action at page 7.

The contentions of the Patent Office as summarized above with respect to the rejected claims are respectfully traversed as described below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation in the references themselves, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The

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teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully submit the Patent Office has not provided a valid suggestion or motivation to combine the references based on the teachings of the references themselves. The Patent Office appears to be arguing that one of skill in the art would be motivated to combine the references because Jacobson et al. and Guttman et al. "remedy the deficiencies" of Mauck. Applicants respectfully submit that in order for one of skill in the art at the time of the claimed invention to be motivated to remedy the alleged specific deficiencies (that is, teach the elements recited in the pending claims) with another reference, one of skill would need hindsight knowledge of the present claims for use as a scaffold in cobbling together the different elements from the various references. The Federal Circuit has stated:

It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

*In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992).

Applicants respectfully submit that the cited references offer no explicit or implicit suggestion to combine the cited references. Further, the only motivation provided by the Patent Office to combine the references appears to be hindsight reconstruction based on the teachings of the present application. As such, it would be improper to combine the references without further motivation found within the references themselves.

In summary, the cited references alone or in combination do not provide a valid motivation to combine the references to arrive at the method recited in Claim 1 or rejected Claims 2-8, 11-13, and 15-19 which depend directly or indirectly from Claim 1. Therefore, applicants respectfully submit that a rejection under 35 U.S.C. § 103 of Claims 1-8, 11-13, and 15-19 based on Mauck in view of Jacobson et al. with

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evidence provided by the '777 Patent and further in view of Guttman et al. is improper. Allowance of Claims 1-8, 11-13, and 15-19 over the cited references is therefore respectfully requested.

#### New Claims

New Claims 34 and 35 have been added by this amendment as indicated above.

Claim 34 is a dependent claim from Claim 1 further reciting that the pores have a diameter of less than 1  $\mu\text{m}$ . Claim 35 is a dependent claim from Claim 34 further reciting that the pores have a diameter of ranging from about 1 nm to about 100 nm. Support for both claims can be found in the specification at page 13, lines 14-20. Therefore, no new matter has been added by the addition of Claims 34 and 35.

It is respectfully submitted that new claims 34 and 35 are allowable over the prior art for the reasons set forth herein above. Allowance of Claims 34 and 35 is therefore respectfully requested.

#### CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

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DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date: 04/05/2005

By:



Arles A. Taylor, Jr.

Registration No. 39,395

1392/10/2/2/3

AAT/JD

Customer No: 25297

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**EXHIBIT A**

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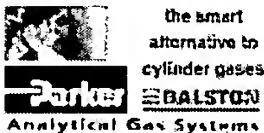
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